K043316

510(k) Summary

FEB - 7 2005

Submitter:	SIGNUS Medizintechnik GMBH Brentanostr. 9 Alzennau, Germany D-63755 49-6023 9166-0
Contact Person:	Tracy L. Gray, RN, BS RAC Principal Consultant Alquest, Inc. Phone: (763) 588-9873 Fax: (763) 287-3836
Date Prepared:	November 22, 2004
Trade Name:	RABEA™
Classification Name and Number:	21 CFR 888.3060
Product Code:	MQP
Predicate Device	Curved PEEK Tetris™ cleared under K041888 on 8/10/04.
Device Description:	The RABEA™ Spinal implant is a rectangular frame. The upper and lower aspects of the implant are open and the walls feature spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The frame is forged from PEEK (PEEK-OPTIMA™ LT1), which is radiolucent, and incorporates small Titanium alloy (TiAl6V4) marker pins so the device can be located within the body. The marker pins meet ASTM F-136 and ISO 5832/3. The RABEA™ Spinal Implant is available in a variety of sizes ranging from 5mm to 30mm. This enables the surgeon to choose the size suited to the individual pathology and anatomical condition. The RABEA™ is implanted in pairs.
Intended Use:	The RABEA™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. This device is intended to be implanted in pairs. The supplemental internal fixation systems that may be used with the RABEA™ Spinal Implant are the same as those used with the Curved PEEK Tetris™ Spinal Implant and include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).
Statement of Technological Comparison	The subject device and predicate device have the following similarities: • The same indication for use; • The same operating principle; • The same basic design; • The same materials; Implanted using the same surgical techniques and equipment;

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2005

Signus Medizintechnik GMBH
C/o Ms. Tracy Gray
Principal Consultant
Alquest, Inc.
4050 Olson Memorial Hwy, Suite 350
Minneapolis, Minnesota 55422

Re: K043316
Trade/Device Name: RABEA™ Spinal Implant
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: November 29, 2004
Received: December 2, 2004

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

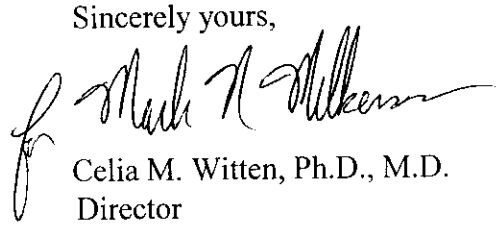
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K043316

Indications for Use Page

510(k) Number (if known): _____

Device Name: RABEA™ Spinal Implant

Indications for Use:

The RABEA™ Spinal Implant is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. This device is intended to be implanted in pairs.

The supplemental internal fixation systems that may be used with the RABEA™ Spinal Implant are the same as the Curved PEEK Tetris™ Spinal Implant and include, but are not limited to, DePuy AcroMed titanium plate or rod systems (Kaneda SR, University Plate, M2, ISOLA, VSP, Moss, TiMX, and Profile).

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043316